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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,745	06/25/2003	Aaron Garzon	87754-7499	9969

28765 7590 11/15/2005

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WASHINGTON, DC 20006

EXAMINER

OWENS, AMELIA A

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,745	<b>Applicant(s)</b> GARZON ET AL.	
	<b>Examiner</b> Amelia A. Owens	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

8-22-05

- 1) ☒ Responsive to communication(s) filed on 7/26/2005
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-20 is/are allowed.
- 6) ☒ Claim(s) 21-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

1. Claims 1-40 are pending.

#### *Claim Rejections - 35 USC § 112*

2. The rejection of claims 1,2,10,11,21,22 are rejected under 35 U.S.C. 112, second paragraph, is dropped as the claims have been amended.
3. Claims 21-40 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons of record.

Applicants' comments have been fully considered but are not found persuasive. The disclosure of the US patents is noted. However, it is what applicants' have disclosed and enabled that is at issue.

Rogawski (reference AG) states -- a diverse group of neurological disorder have been linked to excessive activation of excitatory amino acid receptors. It goes on to list the disorders and to discuss the advantages of N-methyl-D-aspartate (NMDA) receptor antagonists. Rogawski does not teach that NMDA receptor antagonism is an effective treatment of the disease states. Rogawski clearly makes a connection between neurological disorders linked to excessive activation of excitatory amino acid receptors and then names NMDA as an excitatory amino acid receptor. Just because a compound acts at a receptor site does not mean the compound will be effective in treating disease/condition associated with that site. Further, Rogawski is concerned with 2,3-benzodazepines, compounds structurally removed from the claimed cannabinoid derivatives. Motivation is lacking for the skilled artisan to extrapolate the results to structurally removed compounds. It is noted that Balayev (reference AR) teach a cannabinoid derivative, dexamabinol, may be effective in focal cerebral ischemia. See abstract. It is not seen where the skilled artisan is aware of a single NMDA compound effective against the myriad of diseases/disorders claimed by applicant.

Regarding prevention, the disclosure of the present invention is a method of treating and preventing inflammatory diseases or disorders, damage resulting from ischemia, injuries to the central nervous system and neurodegenerative disorders, pain, autoimmune diseases, cardiovascular disorders, or drug abuse, tolerance or dependence, by administering to a patient in need thereof a therapeutically effective amount of a pharmaceutical composition comprising a

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compound of the formula (1). Hence, the amount of guidance presented in the specification the absence of data indicating that the named disease/condition do not occur when the claimed compound of formula (1) is administered, and the state of the prior art indicating that treatment using the claimed compound is possible, all indicate that treatment, not prevention is possible.

The amount of guidance necessary to perform applicant's invention would result in undue experimentation because the skilled artisan would be forced to randomly test numerous disease/condition to determine which ones, of any, could be prevented by administering the claimed compound. See - Can We Prevent Parkinson's and Alzheimer's disease? column 1 @ lines 1-7 that teach no preventive or long term effective strategies are available for Alzheimer's and Parkinson's which are named conditions in claim 33. Clearly all of the diseases encompassed by applicant cannot be prevented.

4. Claims 21-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant method encompasses as yet unidentified diseases/conditions of inflammatory; ischemia; CNS; autoimmune; cardiovascular; drug abuse, tolerance dependence; pain; neurodegenerative - a description of which is not found in the specification.

The instant method encompasses as yet unidentified opioids, psychostimulants - a description of which is not found in the specification.

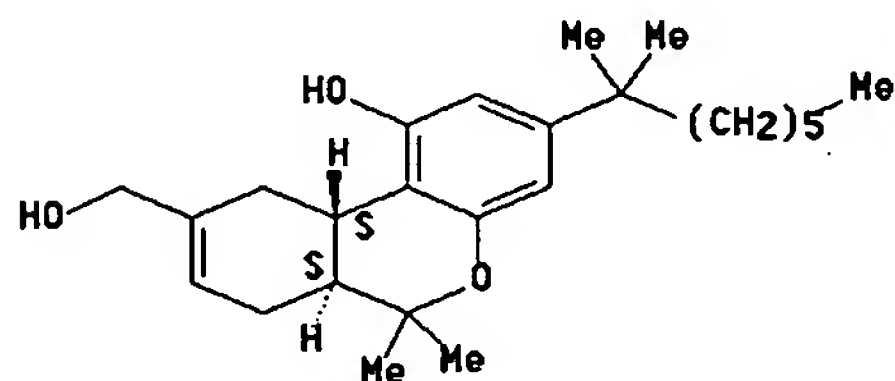
The instant method encompasses as yet unidentified diseases/conditions associated/related to ischemic and inflammatory damage - a description of which is not found in the specification.

The instant method is directed to 'prevention' of as yet unidentified diseases/conditions of inflammatory; ischemia; CNS; autoimmune; cardiovascular; drug abuse, tolerance dependence; pain; neurodegenerative - a description of which is not found in the specification.

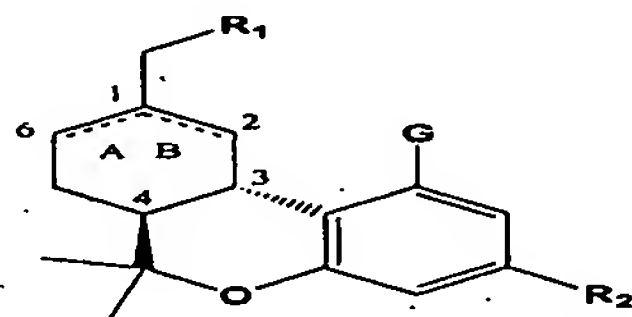
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*Certain Observations*

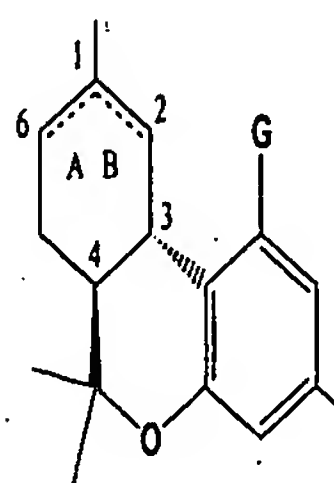
5. Dexanabinol (depicted below) is a synthetic analog of cannabinoid tetrahydrocannabinol that is known to be an antagonist at the N-methyl-D-aspartate (NMDA) receptor. See Belayev et al reference AR submitted by applicant on the PTO-1449.



The claimed compounds have the following formula.



Compounds having the core structure depicted below would be expected to have NDMA activity, as structurally similar compounds would be expected to have similar properties. Thus, the prior art neither teaches nor suggests the claimed compounds. Claims 1-20 are allowable.

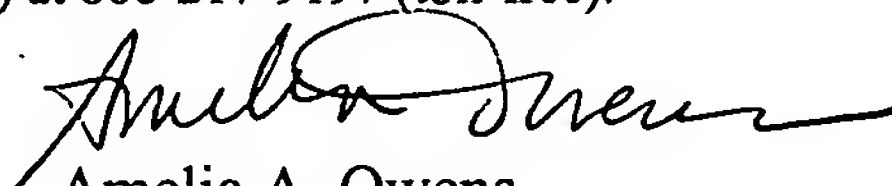


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens  
Primary Examiner  
Art Unit 1625